IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL 2327

THIS DOCUMENT RELATES TO:
Frieda Shahbaz, et al. v. Ethicon, Inc., et al.,
Case No. 2:13-cv-26237

PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Plaintiffs Freida Shahbaz ("Ms. Shahbaz") and Cyrus Shahbaz ("Mr. Shahbaz") (collectively referred to herein as "Plaintiffs") offer the following response in opposition to Defendant's Motion for Partial Summary Judgment, Memorandum in Support of Defendant's Motion for Partial Summary Judgment ("Defendant's MPA"), and the exhibits attached thereto.

I. PROCEDURAL BACKGROUND

Plaintiffs bring the following causes of action against Defendant in this matter: (1) Negligence, (2) Strict liability – design defect, (3) Strict liability – manufacturing defect, (4) Strict liability – failure to warn, (5) Breach of express warranty, (6) Breach of implied warranty, and (7) Loss of consortium. Defendant brings this Motion for Partial Summary Judgment on causes of action (2) through (6) and cause of action (1) – negligence – to the extent it incorporates a claim for negligent failure to warn and negligent manufacturing.[1]

II. STATEMENT OF FACTS

The Local Rules of this District Court do not require numbered paragraphs with admissions of statements of contradiction. Therefore, Plaintiffs will not proceed point-by-point

[1] Based upon subsequent discovery and ruling in the other MDL matters Plaintiffs do not oppose Defendant's motion for summary judgment as to the following: (1) Negligence – to the extent it incorporates negligent manufacturing, (2) Strict liability – design defect, (3) Strict liability – manufacturing defect, (5) Breach of express warranty, and (6) Breach of implied warranty.

through Defendant's Statement of Undisputed Facts. Plaintiffs do not adopt or admit Ethicon's version of the facts, or waive any right to challenge Ethicon's version of the facts. Plaintiffs' account of the pertinent facts is set out fully below.

III. LEGAL STANDARDS

A. Summary Judgment

Summary judgment is appropriate only when "the pleadings, discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact." Fed. R. Civ. P. 56(c). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 255 (1986).

Instead, the court should grant summary judgment "only if taking the evidence and all reasonable inferences drawn therefrom in the light most favorable to the nonmoving party, there is no genuine dispute of material fact, and the moving party is entitled to judgment as a matter of law." *Durham v. Horner*, 690 F.3d 183, 188 (4th Cir. 2012). Thus, the nonmoving party is "entitled 'to have the credibility of his evidence as forecast assumed, his version of all that is in dispute accepted, [and] all internal conflicts in it resolved favorably to him.'" *Miller v. Leathers*, 913 F.2d 1085, 1087 (4th Cir. 1990) (quoting *Charbonnages De France v. Smith*, 597 F. 2d 406, 414 (4th Cir. 1979)).

When a party seeks summary judgment on the basis of an absence of evidence as Defendants do here, "the movant must discharge the burden the Rules place upon him: It is not enough to move for summary judgment without supporting the motion in any way or with a conclusory assertion that the plaintiff has no evidence to prove [her] case." *Celotex Corp., v. Catrett*, 477 U.S. 317, 328 (1986). Defendant's failure to meet this standard is explained in further detail below.

B. Choice of Law

Plaintiffs agree, based on the decisions of California Courts and this Court that California substantive law applies to Plaintiffs' claims. As a result, the proper function of the federal court

in making its decision here, is to ascertain what the state law is, not what it ought to be. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 494, 61 S. Ct, 1020, 1020 (1941).

C. Strict Liability – Failure to Warn and the Learned Intermediary Doctrine

"Our law recognizes that even 'a product flawlessly designed and produced may nevertheless possess suck risks to the user without a suitable warning that it becomes 'defective' simply by the absence of a warning.'… 'Thus, manufacturers have a duty to warn consumers about the hazards inherent in their products. The purpose of requiring adequate warnings is to inform consumers about a product's hazards and faults of which they are unaware, so that the consumer may then either refrain from using the product altogether or avoid the danger by careful use." *Taylor v. Elliot Turbomachinery Co., Inc.*, 171 Cal.App.4th 564, 577 (2009).

California applies its own version of the learned intermediary doctrine to claims of strict liability product defect theorized on a manufacturer's failure to warn. Generally, the learned intermediation doctrine is applicable in California if a direct warning to the consumer would be ineffective. In those instances, the manufacturer fulfills its duty to warn by informing the seller or supplier (who then has an independent duty to warn the consumer), and the manufacturer is not liable to the consumer for failing to warn him/her directly. *Brown v. Superior Court*, 44 Cal.3d 1049, 1062 n.9 (1988). In the context of prescription drugs, manufacturers have a duty to warn the physician, not the patient, of a drug's dangerous propensities. *Carlin v. Superior* Court, 13 Cal.4th 1104, 1116 (1996); *Biegler-Engler v. Berg*, 7 Cal.App.5th 276 (2017).

California courts extended the learned intermediary doctrine to implantable medical devices. *Natmeyer v. Stryker Corp*., 502 F. Supp 2d 1051, 1060 (1999); *Valentine v. Baxter Healthcare Corp.*, 68 Cal.App.4th 349, 359-361; *Biegler-Engler v. Berg*, 7 Cal.App.5th 276 (2017). However, the learned intermediary doctrine does not automatically apply to every instance simply because it involves an implantable medical device. The learned intermediary doctrine applies only if the manufacturer provided an adequate warning to the intermediary. *Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943, 953 (E.D. Cal. 20130).

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D. California Recognizes Strict Product Liability Defect as a Cause of Action

"A manufacturer, distributor, or retailer is liable in tort if a defect in the manufacture or design of its product causes injury while the product is being used in a reasonably foreseeable way." *Soule v. Gm Corp*. 8 Cal.4th 548, 560 (1994). Additionally, "[s]trict liability has been invoked for three types of defects – manufacturing defects, design defects, and 'warning defects' i.e., inadequate warnings or failures to warn." *Anderson v. Owens-Corning Fiberglass Corp*. 53 Cal.3d 987, 995 (1991). To the extent Defendants seek to have Plaintiffs' claim for strict liability product defect premises on Defendant's failure to warn, Defendant's Partial Motion for Summary Judgment fails as a matter of law and should be denied.

IV. ARGUMENT

A. **A Disputed Issue of Material Fact Exists in the Application of the Learned Intermediary Doctrine**.

Defendant does not challenge Plaintiffs' claims that the warnings in place during Plaintiffs' implant surgery were inadequate in the present motion for partial summary judgment. As a result, the inadequacy of the warnings remain in dispute between the parties. As explained above, **the learned intermediary doctrine applies only where the manufacturer provided an adequate warning to the learned intermediary**. *Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943, 953 (E.D. Cal. 20130) (emphasis added). Whether the warnings are inadequate and thus prevent the application of the learned intermediary doctrine is an issue for the trier of fact. *Bryant v. Tech. Research Co.*, 654 F.2d 1337, 1339 (9th Cir. 1981) ["The adequacy of a warning is a question for the trier of fact, and a manufacturer's warning to its intermediary is only one factor for the jury to consider."].

Plaintiffs will present evidence at trial that the warning provided by Defendant at the time Ms. Shahbaz was implanted with Ethicon Prolene Soft mesh was inadequate and did not properly put physicians on notice of the type or severity of risks associated with the Ethicon Prolene Soft mesh. Specifically, Plaintiffs' case-specific expert Dr. Ja-Hong Kim (urogynecologist) states in her report, which was previously served on Defendant, the following:

> "For a surgeon to properly inform the patient of all the known risks included in any procedure involving an implantable medical device, the surgeon relies upon the manufacturer to have scientific knowledge of and convey all characteristics of its products that could impact safety and efficacy. Specifically, surgeons rely on the "Adverse Events/Risks" section of a medical device IFU to gain scientific knowledge regarding adverse events or undesirable effects that the company knows are associated with the product. I am familiar with and have reviewed and used IFUs in my own practice. I have reviewed the Ethicon Prolene Soft mesh IFU. Ethicon failed to include and/or describe the significant adverse events and risks in its Instruction for Use (IFU) for the Ethicon Prolene Soft mesh. Despite having specific and scientific knowledge of the adverse reactions and risks when the Ethicon Prolene Soft mesh first arrives on the market, Ethicon did not fully inform physicians of these dangers. As a result, physicians were unable to fully inform patients of the risks associated with Ethicon Prolene Soft mesh and pateitns were unable to give their full consent to the procedure. As Mrs. Shahbaz states in her deposition, Dr. Raz did not have give (sic.) detailed risk profile of the mesh product because there was incomplete information available to Dr. Raz. The risks that Ethicon did describe in the IFU were mischaracterized to minimize the actual risk to patients. When Ethicon was given every opportunity to update the IFU, and in the face of specific requests to do so from various medical professionals, Ethicon failed to make the necessary updates. To a reasonable degree of medical certainty, these failures prevented physicians and patients from having the ability to make an informed choice regarding the use of the Ethicon Prolene Soft mesh." (*See* Report of Dr. Ja-Hong Kim, attached hereto as "**Exhibit A**").

Defendant provided no California law that supports the presumption that the learned intermediary doctrine automatically applies without first determining the adequacy of the warnings. As a result, Defendant's motion for partial summary judgment as to Plaintiffs' claims based on that theory (including breach of express warranty and breach of implied warranty) should be denied.

B. **Plaintiffs' Failure-to-Warn-Based Claims Do Not Fail Because Causation is a Disputed Issue**.

Plaintiffs contend that the inadequate warning contained in the Ethicon Prolene Soft mesh IFU was a substantial factor in Dr. Raz's decision to recommend and implant Mrs. Shahbaz with Ethicon Prolene Soft mesh **and** in Plaintiff's decision to consent to the mesh implant procedure. (*See* Declaration of Frieda Shahbaz, attached hereto as "**Exhibit B**"). Plaintiffs have designated Dr. Raz as a non-retained expert on the following: "Opinions on **causation**, diagnoses, prognosis, and extent of disability based upon his treatment of Freida Shahbaz." (*See* Plaintiffs' expert designation, attached hereto as "**Exhibit C**"). Plaintiffs intend to call Dr. Raz at trial to

elicit testimony that he no longer implants women with vaginal mesh of any kind given the information he has learned over the years regarding its significant risks, which were not contained in the IFU at the time he performed Plaintiff's implant surgery in 2007. Dr. Raz also performed Plaintiff's explant surgery in 2011.

Dr. Raz's opinions regarding pelvic mesh are well known. In a deposition given July 25, 2012 against Ethicon in New Jersey State Court, Dr. Raz testified that, "I used mesh in the past, and I abandoned mesh because I've seen patients seven to ten years later with now appearing with erosions and complications, so I decided to – not to use the mesh." (*See* excerpt from the deposition of Dr. Raz [Wicker v. Ethicon, Atlantic County Superior Court Docket no. ATL-L-6951-10], attached hereto as "**Exhibit D**"). In a deposition given January 21, 2015 in Missouri State Court, Dr. Raz testified that, "Because I did mesh in the past only for urethra sling let's say. And now five, 10 years later, patients have come in with complications. Pain, erosion, infection. And there's an ongoing process of the mesh. And for that reason I decided not to use for the last three years, I don't use any mesh." (*See* excerpt from the deposition of Dr. Raz [Sherrer v. Truman Medical, Jackson County Circuit Court Docket no. 1215-CV27879], attached hereto as "**Exhibit E**"). In a deposition given June 7, 2017 against AMS in the MDL, Dr. Raz testified that, "I abandoned mesh four or five years ago" due to "[l]ate complications of patients that did very well at the beginning." (*See* excerpt from the deposition of Dr. Raz [Ordonez v. AMS, Southern District of West Virginia Case No: 2:12-cv-09084], attached hereto as "**Exhibit F**"). In or around 2012, Dr. Raz "abandoned" mesh due to its complications. Therefore, Dr. Raz would not have implanted Plaintiff with Prolene Soft mesh in 2007 if he knew then what he knows today regarding its complications (i.e. pain, erosion, and infection).

As stated in Dr. Kim's case-specific expert report, "Ethicon failed to advise Mrs. Shahbaz's implanting physician of the adverse events and risks associated with the Ethicon Prolene Soft mesh. While Dr. Raz consented Mrs. Shahbaz for the procedure, she could not have properly done so because she was not fully aware of the adverse events and risks associated with the Ethicon Prolene Soft mesh." (*See* "**Exhibit A**"). As stated in her declaration, Plaintiff would

not have consented to the procedure implanting Prolene Soft mesh if she had known about the risk of erosion. (*See* "**Exhibit B**").

"In addition, if Dr. Raz had been made aware of the increased risk of failure of the Ethicon Prolene Soft mesh, he could have made a choice to use a more studied device. Because Ethicon had knowledge of these risks, they should have included them in the IFU, so that Dr. Raz could perform an appropriate risk-benefit analysis. As a result, to a reasonable degree of medical certainty, it is my [Dr. Kim's] opinion Mrs. Shahbaz was damaged as a result of injuries she suffered that were not disclosed to her consulting and implanting physicians by Ethicon. (*See* "**Exhibit A**").

Dr. Raz's abandonment of the use of mesh in his patients from 2012-present due to complications such as pain, erosion, and infection, along with Plaintiffs' statement that she would not have consented to the procedure had she been aware of complications such as erosion, is clear evidence that Ethicon's failure to warn of mesh complications – including erosion – caused Plaintiffs' injuries.

V. CONCLUSION

Plaintiffs oppose Defendant's Motion for Partial Summary Judgment to the extent that it seeks summary adjudication of the failure to warn component of Plaintiffs' strict product liability and negligence causes of action (as well as the warranty-based claims which are premised upon a failure to warn theory). Defendant's motion should be denied as to those theories.

Dated: October 25, 2018

GIRARDI KEESE

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of October, 2018, I electronically filed the foregoing document with the Court using CM/ECF. I also certify that the foregoing document is being served on this day on all counsel of record via transmission of Notices of Electronic Filing generated by CM/ECF or by other means.

By: /s/ Carlos Urzua
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